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10/784,462

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

01/27/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--|-------------------------------------|--|
| Office Action Summary | Application No. 10/784,462 | Applicant(s) BERRA ET AL. | |
| | Examiner Brian E. Pellegrino | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-109 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-21, 24-29, 40-60, 65-67, 70-72, 75-77, 80-82, 85-87, 90-92 and 95-97 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 7-9, 22, 23, 30-39, 61-64, 68, 69, 73, 74, 78, 79, 83, 84, 88, 89, 93, 94 and 98-109.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4,10,11,40,47,65-67 are rejected under 35 U.S.C. 102(b) as being anticipated by Quinn (6319278). Fig 5 shows a vascular repair device having a tubular graft body **61**, a structural framework having at least two Z-stents **42,44**. Fig. 4 illustrates there can be a longitudinal support **48** that is curved in an S-shape and connected to the graft body. Thus, the support member when viewed in an orientation that the longitudinal axis and centerline of the support member are aligned it can be said that the support member is substantially reverse-mirror symmetrical with respect to the longitudinal axis. It can also be construed that since the longitudinal support wraps or extends in a lateral direction, it has a partial helix shape. Quinn discloses the support is made of metal, such as stainless steel, col. 2, lines 30,31. Since the support is part of the framework, it is preformed in the curved shape. Additionally, since the ends of the support are welded, they form rounded end as seen in Fig. 2. The stent clearly has a linear profile and Quinn discloses the device having a circular cross-section, col. 2, lines 43-46. Regarding claim 47, the graft is fully capable of having a diameter of the vessel it is implanted in once the stent graft is expanded.

Claims 1-4,6,10,14,15,18,19,40,41,43,47,49,53,65-67,70-72,80-82 are rejected under 35 U.S.C. 102(b) as being anticipated by Philips et al. (WO 99/37242). Fig. 12 shows a stent graft having a graft body **S** and having multiple Z-stents **F** (or rings of zig-

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zags) connected to the graft body. It can also be seen there is a curved wire running the middle area to form a longitudinal support member, independent of the stents and along the sides also, page 28. This wire when viewed in an orientation that the longitudinal axis and centerline of the support member are aligned it can be said that the support member is substantially reverse-mirror symmetrical with respect to the longitudinal axis and the centerline. The longitudinal support wire is shorter than the entire support structural framework. It can also be construed that since the longitudinal support wraps or extends in a lateral direction, it has a partial helix shape. Philips et al. disclose the support wire is made of metal, such as nitinol, page 19, last paragraph. The wire support is fully capable of being preformed into a curved shape. Regarding claim 18, since there are end stents **M** and the wire support member does not extend the entire distance between these end stents, the stent graft forms a gimbal at an end. Regarding claims 47,49,53, Philips discloses the graft body has a diameter at least as large as the diameter of the vessel in which it is implanted, page 27. Regarding claims 66,71,81, since the stent graft has a length, clearly the stents have linear longitudinal profiles. With respect to claims 67,72,82, Philips also discloses the graft body is tubular, thus the stents are circular, pages 14,27.

Claims 25-29,45,46,57,59,90-92,95-97 are rejected under 35 U.S.C. 102(a,e) as being anticipated by Van Schie (2003/88305). VanSchie shows a stent graft having a plurality of stents with the middle stents being considered as inner stents and a tubular graft body **2** surrounding the stents. It can also be seen there is a curved longitudinal support member **8** connected to the graft independent of the stents and has rounded

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ends **9,10**. It can also be interpreted that the longitudinal support member that is curved and is capable of being partially curved about the circumference of the graft body since it is a flexible graft and can be twisted. Van Schie also discloses the longitudinal member can even be shorter or extend less than the distance between the end stents, paragraph 47. Van Schie et al. disclose the support member is a polymer or metal and is pre-formed in a curved shape, paragraph 45. The support member is substantially symmetrical with respect to a centerline that is about the middle of the device going around the circumference. It can be construed that the rounded ends are curved extremities and “substantially asymptotic”. Regarding claims 91,96, Fig. 5 shows the stents have a linear profile. With respect to claims 92,97, it can be seen (Fig. 4) that the stents have a circular cross-sectional shape.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 5,12,13,16,17,42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Philips et al. (WO 99/37242) in view of Bolea et al. (6821291). Philips is explained supra. However, Philips fails to disclose the longitudinal member has looped ends at the extremities. Bolea et al. teach (Fig. 22) a stent with a wire member having looped extremities **184**. Bolea et al. also teach that the loops enable an end to be collapsed to remove the stent device, col. 10, lines 31-36. It would have been obvious to one of ordinary skill in the art to use looped ends on a longitudinal wire

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support member as taught by Bolea et al. and incorporate into the stent graft of Philips et al. to provide the ability to remove the prosthesis if necessary.

Claims 16,17,51,75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Schie et al. (2003/88305) in view of Bolea et al. (6821291). Van Schie et al. is explained supra. However, Van Schie et al. fail to disclose the support member extremity is curved back on itself. Bolea et al. teach (Fig. 18) that wire support members are curved back on themselves to form loops **170** to retrieve the stent at a later time, see entire patent for reason of loops. It would have been obvious to one of ordinary skill in the art to modify the extremities of the longitudinal support member as taught by Bolea et al. in the stent graft of Van Schie et al. such that the ability to retrieve the stent graft can be accomplished easily if the need arises in the patient.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn '278 in view of Baker et al. (6346118). Quinn is explained supra. However, Quinn fails to disclose a distal most stent with an apex more than another of stents. Baker et al. teach (Fig. 21) a stent graft with a distal stent having an apex more than another of the stents. Baker et al. also teach that the farthest apex allows for better seals in a wall of a vessel, col. 12, lines 37-45. It would have been obvious to one of ordinary skill in the art to use stents with a farther apex than other stents to better anchor in the vessel as taught by Baker et al. and incorporate into the stent graft of Quinn to improve the seal of the graft against the vessel wall.

Claims 48,50,54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Philips et al. (WO 99/37242) in view of Baker et al. (6346118). Philips is explained

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supra. However, Philips fails to disclose a distal most stent with an apex more than another of stents. Baker et al. teach (Fig. 21) a stent graft with a distal stent having an apex more than another of the stents. Baker et al. also teach that the farthest apex allows for better seals in a wall of a vessel, col. 12, lines 37-45. It would have been obvious to one of ordinary skill in the art to use stents with a farther apex than other stents to better anchor in the vessel as taught by Baker et al. and incorporate into the stent graft of Philips et al. to improve the seal of the graft against the vessel wall.

Claims 58,60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Schie et al. (2003/88305) in view of Baker et al. (6346118). Van Schie et al. is explained supra. However, Van Schie fails to disclose a distal most stent with an apex more than another of stents. Baker et al. teach (Fig. 21) a stent graft with a distal stent having an apex more than another of the stents. Baker et al. also teach that the farthest apex allows for better seals in a wall of a vessel, col. 12, lines 37-45. It would have been obvious to one of ordinary skill in the art to use stents with a farther apex than other stents to better anchor in the vessel as taught by Baker et al. and incorporate into the stent graft of VanSchie et al. to improve the seal of the graft against the vessel wall.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Schie et al. (2003/88305) in view of Bolea et al. '291 as applied to claim 16 above, and further in view of Baker et al. '118. Van Schie et al. as modified by Bolea et al. is explained as before. However, Van Schie et al. in view of Bolea et al. fail to disclose a stent with an apex more than another of the stents. Baker et al. is explained supra. It would have been obvious to one of ordinary skill in the art to incorporate a farther apex

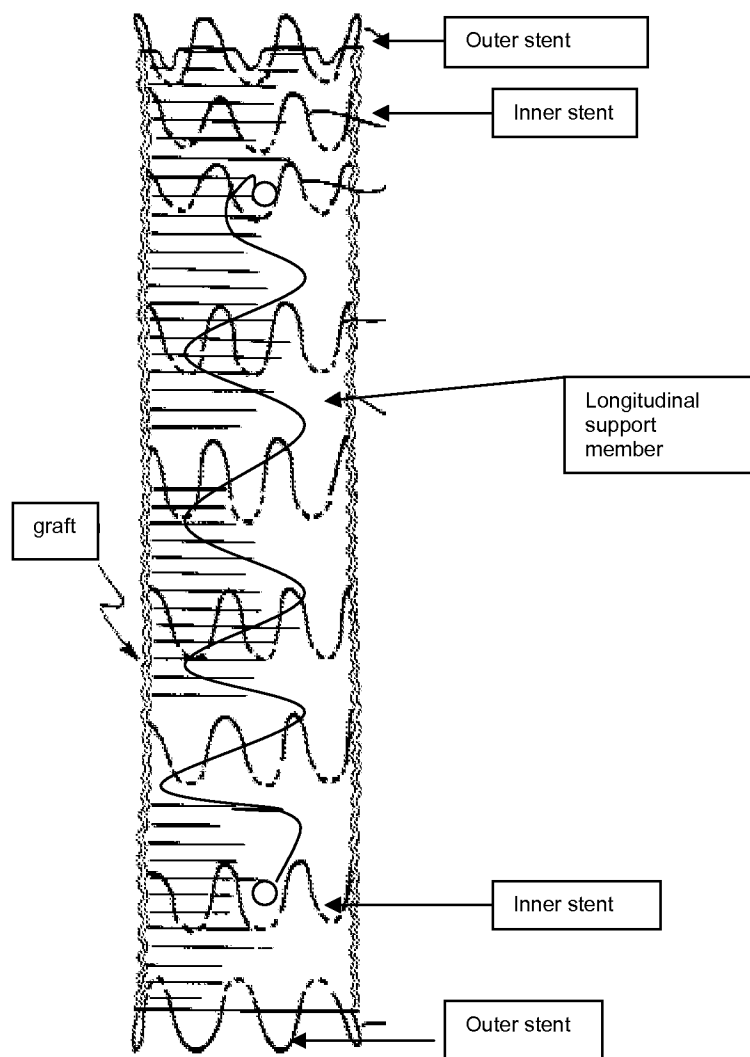
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on a distal stent as taught by Baker et al. with the stent graft of Van Schie et al. as modified by Bolea et al. such that it enhances the seal within the vessel wall.

Claims 18,19,20,21,24,25-29,44,53,55,57,59,80-82,85-87,90-92,95-97 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. (6099558) in view of Jayaraman (6464719). White et al. disclose a stent graft (Fig. 3) with a plurality of stents **17** and a tubular graft body **16**. It can also be seen (Fig. 2) that the stent graft has a distal and proximal stents **17a** that extend beyond the graft material and thus are outer stents. Regarding claims 53,55,57,59, White shows the graft body **10a,10b** has a diameter at least as large as a diameter of a normal vessel, **12,13** in which it is placed. However, White et al. fail to disclose a longitudinal support member. Jayaraman teaches (Fig. 8) a longitudinal support member 53 that is curved and shorter than the body of the stent graft and since it is joined to the graft, it is not touching the stents. Thus, by having the shorter length of the body of the stent graft it provides a gimbal. Jayaraman also teaches (Fig. 7) that the support members have looped ends **55**. Jayaraman additionally teaches that the longitudinal members have what can be construed as a partial helix shape or S-shapes joined together and used in expansion and made of nitinol, col. 2, lines 3,4,37,38. It is also noted that Jayaraman shows (Figs. 3,4) that the longitudinal curved members are connecting pieces for stent sections, col. 3, lines 29,30,53,54. It would have been obvious to one of ordinary skill in the art to use curved longitudinal support members as taught by Jayaraman in the stent graft of White et al. such that it provides more support to the vessel walls and assist in expansion and keep the stent in its expanded form together. Because Jayaraman's support member

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does not extend to the end of the graft, it can be said that it does not touch the first set of inner stents as illustrated below in the modified stent graft of White in view of Jayaraman's teaching. Also it is noted that the use of "substantially" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. Thus, the support member of Jayaraman as incorporated into White's stent graft can be "substantially" reverse-mirror symmetrical.



Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quinn '278 in view of Baker et al. (6346118). Quinn is explained supra. However, Quinn fails

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to disclose a distal most stent with an apex more than another of stents. Baker et al. teach (Fig. 21) a stent graft with a distal stent having an apex more than another of the stents. Baker et al. also teach that the farthest apex allows for better seals in a wall of a vessel, col. 12, lines 37-45. It would have been obvious to one of ordinary skill in the art to use stents with a farther apex than other stents to better anchor in the vessel as taught by Baker et al. and incorporate into the stent graft of Quinn to improve the seal of the graft against the vessel wall.

Claims 54,56,58,60 are rejected under 35 U.S.C. 103(a) as being unpatentable over White et al. '558 in view of Jayaraman '719 as applied to claims 18,20,25,28 above, and further in view of Baker et al. '118. White as modified by Jayaraman is explained as before. However, White in view of Jayaraman fail to disclose a stent with an apex more than another of the stents. Baker et al. is explained supra. It would have been obvious to one of ordinary skill in the art to incorporate a farther apex on a distal stent as taught by Baker et al. with the stent graft of White as modified by Jayaraman such that it enhances the seal within the vessel wall.

Response to Arguments

Applicant's arguments filed 10/16/08 have been fully considered but they are not persuasive. First Applicant argues the rejection over Quinn '278 and states the graft is not connected to the stent. Applicant is mistaken and has not reviewed the reference in its entirety because on col. 3, lines 3,4,7,8,11,12 and thus the Examiner maintains the rejection. If the support member is connected to the Z-stents and the Z-stents are

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connected to the graft, then logically the support member is also considered connected to the graft body. Additionally Applicant argues the support member of Quinn cannot be reverse-mirror symmetrical. However, it might be helpful to review the language of the claim which recites the "support member is substantially reverse-mirror symmetrical with respect to the longitudinal axis". Applicant must be reminded that the use of "substantially" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. Thus, the support member of Quinn can be "substantially" reverse-mirror symmetrical.

Applicant then argues the rejection over Phillips stating the rejection of the claims is not shown because Phillips is alleged to use a single wire to form the zig zag formation. Applicant alleges the claimed invention is different Z-stents. The Examiner is entitled to give terms in a claim its plain meaning as interpreted by one of ordinary skill in the art. It is noted that the specification must clearly set forth the definition explicitly and with reasonable clarity, deliberateness, and precision. Exemplification is not an explicit definition. Even explicit definitions can be subject to varying interpretations. See *Teleflex, Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374, 1381 (Fed. Cir. 2002), *Rexnord Corp. v. Laitram Corp.*, 60 USPQ2d 1851, 1854 (Fed. Cir. 2001) and MPEP 2111.01. While it is noted that the specification mentions Z-stents (paragraphs 8,152) it is noted that Applicant provides no definition as to what is meant by the term. The specification mentions a Z-stent is a zig zag. It does not state that it cannot be rings of zig-zags connected. Thus, Phillips can be said to have a plurality of Z-stents and Phillips does not exclude the possibility of separate rings, despite that is not required by

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the language of the claims. Additionally Applicant argues that Phillips does not disclose a gimbaled end. However, the claim only requires at least one end being gimbaled and it can be seen that at least end **2** of Phillips embodiment in Fig. 12 is gimbaled since the end stents are separate from the reinforcement filament forming z-stent rings about the graft body.

Applicant then argues the rejection over Van Schie stating that it does not disclose a circumferentially disposed support member. However, the curved support member of VanSchie's stent graft is fully capable of having a "portion" circumferentially about the graft when the graft is twisted or deployed through curved vessels as illustrated and disclosed in VanSchie. Applicant also argues that the support member is not disclosed to not touch the inner stent. The Examiner respectfully disagrees since Van Schie clearly discloses a shorter support member. Since the illustration in the drawings is a finite perspective, it must be clarified to Applicant that upon having the support member disclosed (paragraph 47 of VanSchie) to be shorter, logically there must be a plurality of ring or z-stents that extend beyond the dimensions of the support member such that there is an inner stent that will not touch the support member.

In response to applicant's argument that the ends of the support member are curved back on itself to form an extremity, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicant alleges the Phillips and VanSchie references are not combinable with Bolea's

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teaching since they would teach away or are non-analogous. It is well known that from time to time during surgery a surgeon may need to reposition the stent graft. Bolea clearly provides the feature of a curved back extremity on a wire for giving the surgeon an accessible means to grasp onto and move or reposition the stent. It is also known that stents may fail and need to be replaced or removed from vasculature and again Bolea teaches that providing a feature of a curved back loop extremity on a wire would enable a surgeon to grab onto a stent and remove it from the body vessel. Therefore, one of ordinary skill would be led to consider incorporating a curved back extremity on a longitudinal support member in the devices of Phillips and VanSchie such that the surgeon can grab onto the stent and retrieve it if necessary.

Applicant argues the rejection of White with Jayaraman by alleging the Jayaraman reference teaches placement of longitudinal reinforcement members all the way to the ends. However the Examiner respectfully disagrees because if this was so then the drawing that Applicant interprets this from (Fig. 8) would have more of the longitudinal member shown at the end and the distal tip would show at the ends of the mesh or graft body. The Examiner proposes it can only be said it is located proximal to an end, but not to the end. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a

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reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). Clearly one of skill in the art would know how to incorporate the longitudinal member of Jayaraman into the stent graft of White since it would only involve routine skill in the art. People of ordinary skill in the art are cardiac surgeons and engineers in developing and finding the appropriate treatment means for a patient, and are familiar with the risks and complications involved with any cardiac procedure such as delivery and the vasculature pathways encountered. A person of ordinary skill is also a person of ordinary creativity, thus it would have been obvious to one of ordinary skill (a cardiac surgeon and engineer) in the art to use known means, i.e. suturing the longitudinal member to the graft as taught by Jayaraman in the device of White such that it would be flexible enough to go through tortuous vessels but retain its rigidity to support the vessel walls.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E. Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M- F (7am-5:30pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TC 3700

/Brian E Pellegrino/

Primary Examiner, Art Unit 3738